Title: Veterinary Rabies Reference Vaccine, killed virus - Lot ID 08-14
Author: APPPATTERSON Document Number: CVB-DAT-0418.04



Release Date: 15 Aug 2019

Animal and Plant Health Inspection Service

## Veterinary Rabies Reference Vaccine, killed virus - Lot ID 08-14

**Veterinary Services** 

Center for Veterinary Biologics

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**Author:** APPPATTERSON

**Section/Area:** CVB-DAT

**Release Date:** 15 Aug 2019

Notes: Strain/Source: Pasteur Virus, Fill Date: November 24, 2008

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## United States Department of Agriculture Animal and Plant Health Inspection Service Center for Veterinary Biologics P. O. Box 844 Ames, IA 50010

1. Reagent Name: Veterinary Rabies Reference Vaccine, killed virus

2. Strain or Source: Pasteur Virus

**3. Lot Number:** 08-14

**4. Fill Date:** November 24, 2008

**5. Expiration Date:** January 31, 2020

**Precautions:** There are no known hazards associated with the use of this reagent.

- **6. Intended Use:** For use as a reference vaccine in the title 9, *Code of Federal Regulations*, (9 CFR), part 113.209 testing.
- 7. **Instructions for Use:** Reference the current edition of the World Health Organization's Laboratory Techniques in Rabies; *The National Institute of Health's (NIH) Test for Potency*; or the Center for Veterinary Biologics (CVB) Supplemental Assay Method 308 for use and formulations.

Reconstitute 1 vial with 13 mL sterile distilled water. This reference vaccine is for use in the NIH test. Starting with undilute, 5-fold dilutions (1:1 through 1:625) are made in phosphate buffered saline and these dilutions of the reference are used to vaccinate mice. Discard the remaining reconstituted reference.

For the second vaccination, reconstitute a new vial of reference with 13 mL sterile distilled water. Prepare 5-fold dilutions as described previously and immunize mice. Discard the remaining reconstituted reference.

- **8. Test of Reagent:** Lot 08-14 was negative for viable rabies virus by intracerebral inoculation of mice and rabbits by 9 CFR 113.209(d)(2)(i). The vaccine was found to be free of mycoplasma and bacteria by 9 CFR 113.26 and 113.28 testing. The residual moisture content of the vaccine was equal to 3.9% by 9 CFR 113.29. The initial dilution value was determined by calibrating against the 6th International Rabies Reference vaccine in the NIH test.
- 9. Container Size, Type, Weight, or Volume: 5 mL (lyophilized) in a 20-mL glass serum bottle.

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- 10. Storage Conditions: Store at  $-20^{\circ} \pm 4^{\circ}$ C.
- 11. **CVB Technical Contact:** Alethea Fry (515) 337-7460, Virology Section, Center for Veterinary Biologics.
- 12. Origin and Passage History: The virus is the Pasteur Virus strain.
- **13. Method of Preparation:** Lot 08-14 was grown in baby hamster kidney (BHK-21) cells. Following 5 days of incubation, the virus was inactivated with beta-propiolactone. The vaccine was tested for purity and inactivation. The reference was bottled, lyophilized, sealed, and stored at -20°C.
- 14. Other: None

**Restrictions:** (optional)

Reagent orders and feedback should be sent *including phone number* to the following email address: VS.DB.CVB.Reagent.Requests@usda.gov

Reagent orders forms (APHIS Form 2018) can be found on the Biologics Forms page of the CVB website.

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